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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,105	06/20/2003	J. Fernando Bazan	DX0903K1B US	7017

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PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
SKELDING, ZACHARY S	
ART UNIT	**PAPER NUMBER**
1644	
MAIL DATE	**DELIVERY MODE**
10/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,105	BAZAN ET AL.	
	Examiner	Art Unit	
	Zachary Skelding	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,23-27 and 41-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,23-27 and 41-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8-8-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment to the claims, filed August 8, 2007, has been entered.

   Claims 23-27, 41 and 42 have been amended.

   Claims 1-20, 22 and 28-40 have been canceled.

   Claims 21, 23-27 and 41-44 are pending.

   Claims 21, 23-27 and 41-44 are under examination as they read on an antibody or fragment thereof that binds SEQ ID NO: 2.

2. This Office Action is in response to Applicant's amendment to the claims and remarks filed August 8, 2007.

   The rejections of record can be found in the previous Office Action, mailed May 3, 2006.

   All prior objections and rejections not mentioned below have been withdrawn.

3. As stated in the prior Office Action mailed February 9, 2007, applicant is advised that the instant claims can only receive benefit under 35 U.S.C. § 120 or § 119(e) of an earlier application date if the earlier application provides support for the instant claims under 35 U.S.C. § 112, 1st paragraph.

   The instant specification and the application from which it is a divisional, 09/963,347, filed September 25, 2001, provide support under 35 U.S.C. § 112, 1st paragraph for the instant claims.

   However, with respect to the claims under examination, the applications to which 09/963,347 claims the benefit of priority do not meet the requirements of 35 U.S.C. § 112, first paragraph, essentially for the reasons given in the prior Office Action, and as outlined further below.

   Thus, the effective priority date of the instant claims is considered to be the filing date of 09/963,347, ***September 25, 2001.***

4. Claims 21, 23-27 and 41-44 stand rejected under 35 U.S.C. 102(e) as anticipated by Sims et al. (US Patent 6,555,520, previously cited), as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan et al. (J. Histochem. Cytochem. 1995; 43:881-886), essentially for the same reasons set forth in the Office Action mailed February 9, 2007.

Applicant argues that the earliest filed application to which the instant application claims the benefit of priority, 60/101,318, filed September 21, 1998, sets forth a specific, substantial and credible utility for the instantly claimed invention.

Therefore, applicant argues that Sims is not valid prior art because Sims' 102(e) date is November 13, 1998, which does not predate applicant's earliest filed provisional application 60/101,318, filed September 21, 1998.

Applicant's arguments have been fully considered but are not persuasive, essentially for the same reasons set forth in the Office Action mailed February 9, 2007.

Applicant traverses the rejection on the premises that IL-B50 has structural similarity to the known polypeptide IL-7 and that the provisional application filed in 1998 states that "[I]t is likely that IL-B50 has either stimulatory or inhibitory effects on hematopoietic cells", therefore, patent of Sims et al. is not a proper 102(e) art (page 7 of the Response). Applicant further refers to the Declaration of Dr. Sali to support this argument.

Applicant's arguments and the Declaration of Andrej Sali under 37 CFR 1.132 filed on August 8, 2007 have been considered but they have not been found convincing to overcome the instant rejection based upon 35 U.S.C. 102(e) as set forth in the Office Action mailed February 9, 2007 for reasons set forth below.

The instant specification and the application from which it is a divisional, 09/963,347, filed September 25, 2001, provide support under 35 U.S.C. § 112, 1st paragraph for the instant claims.

However, with respect to the claims under examination, the applications to which 09/963,347 claims the benefit of priority do ***not*** meet the requirements of 35 U.S.C. § 112, first paragraph in that the skilled artisan would not know how to ***use*** the claimed antibodies that bind SEQ ID NO: 2 as required by 35 U.S.C. § 112 and 35 U.S.C. § 101.

More particularly, USSN 09/399,492, and the applications to which it claims the benefit of priority, 60/131,298 and 60/101,318 (to be referred to henceforth as the '318 provisional), do not provide sufficient support under 35 U.S.C. § 112, 1st paragraph for the instant claims.

The declaration of Dr. Sali states at section 5 that "I was asked to review the '318 provisional application to determine if a person of skill in the art at the time that the application was filed would have considered the statement relating to the ability of IL-B50 to stimulate or inhibit T cells and B cells to be credible in view of the disclosed similarities between IL-B50 and IL-7."

The declaration then goes on to describe how the Declarant would have considered IL-7 and IL-B50 to have had statistically significant sequence similarities as of 1998, concluding that based on this analysis, "...I would have believed that IL-B50 and IL-7 have similar sequences and biological functions. Accordingly, I would have found the utility asserted in the '318 provisional application to be credible." (see declaration section 13).

First, with respect to section 5 of the declaration which states (emphasis added), "I was asked to review the '318 provisional application to determine if a person of skill in the art at the time that the application was filed would have considered ***the statement relating to the ability of IL-B50 to stimulate or inhibit T cells and B cells*** to be credible..." it is not clear what is meant by the highlighted phrase in that it is unclear what "the statement" refers to. It is critical to understand what the Declarant is attesting to in order to understand the meaning of the declaration. For example, "the statement" in the '318 application that seems to most closely resemble what is put forth in section 5 of the declaration is the following: "[i]t is likely that IL-B50 has either stimulatory or inhibitory effects on hematopoietic cells, including, e-g., lymphoid cells, such as T-cells, B-cells, natural killer (NK) cells, macrophages, dendritic cells, hematopoietic progenitors, etc." (see '318, page 9, 1st paragraph)." However, the declaration only mentions the "the ability of IL-B50 to stimulate or inhibit T cells and B cells" and does not mention the other cell types so it is unclear what is being attested to in the Declaration.

However, for examination purposes it will be assumed that the declaration is referring to the following assertion of utility in the '318 provisional application: "[i]t is likely that IL-B50 has either stimulatory or inhibitory effects on hematopoietic cells, including, e-g., lymphoid cells, such as T-cells, B-cells, natural killer (NK) cells, macrophages, dendritic cells, hematopoietic progenitors, etc." (see '318, page 9, 1st paragraph)."

Similarly, the declaration is further unclear in that the conclusion statement of section 13 is also vague and unclear.
On the one hand, section 5 of the declaration refers to Dr. Sali's determination if "the ability of IL-B50 to stimulate or inhibit T cells and B cells [is] credible in view of the disclosed similarities between IL-B50 and IL-7.").
On the other hand, the conclusion statement in section 13 of the declaration is vague in that it is unclear what exactly Dr. Sali is concluding, i.e., does "...I would have believed that IL-B50 and IL-7 have similar sequences and biological functions," mean that Dr. Sali would have believed that IL-B50 *stimulates*, and by inference does *not* inhibit, T cells and B cells, as IL-7 was known to do at the time of the invention as evidenced by applicant's statement at page 9, 2nd paragraph of their Remarks filed August 8, 2007? If so, then this conclusion is narrower than that which Dr. Sali was asked to determine as put forth in section 5, i.e., if "the ability of IL-B50 to *stimulate or inhibit* T cells and B cells [would have been] credible in view of the disclosed similarities between IL-B50 and IL-7," notwithstanding the fact that what exactly Dr. Sali was being asked to determine in section 5 is unclear in and of itself as stated above.

Setting aside the uncertainty about exactly what conclusions are being put forth in Dr. Sali's declaration, the issue at hand is does the '318 application sufficiently disclose a specific, substantial and credible patentable utility for the claimed invention?

Based upon the similarity between IL-B50 and IL-7, the '318 application discloses that the IL-B50 polypeptide would be functionally similar to IL-7 and related cytokines, such as other members of the hematopoietin family of four-helix bundle cytokines to which IL-7 belongs (see the '318 application at page 12 to page 13, 1st paragraph and Janeway et al., Immunobiology, 3rd Ed., Garland Science, pp. A:11 (1997). As was well known in to one of ordinary skill in the art, the hematopoietin family of cytokines encompasses a wide and diverse range of activities (see Janeway et al., *ibid*).

The '318 specification further discloses that "[i]t is likely that IL-B50 has either stimulatory or inhibitory effects on hematopoietic cells, including, e-g., lymphoid cells, such as T-cells, B-cells, natural killer (NK) cells, macrophages, dendritic cells, hematopoietic progenitors, etc." (see '318, page 9, 1st paragraph)."

However, these are ***general activities that would apply to virtually any member of the hematopoietin family of cytokines***, and are ***not specific to the IL-B50 polypeptide***.

In order to discover how to use the claimed antibodies, a skilled practitioner would have to perform significant amount of further research to discover what is, if any that particular effect that IL-B50 shares with IL-7. Thus, at the time of filing, to employ antibodies of the instant invention to ***either stimulate or inhibit*** "hematopoietic cells, including, e-g., lymphoid cells, such as T-cells, B-cells, natural killer (NK) cells, macrophages, dendritic cells, hematopoietic progenitors, etc." would be to use such antibodies as the object of further research, which has been determined by the courts to be a utility which, alone, does not support patentability.

The disclosure of the structure of the IL-B50 polypeptide alone, and the assertion that it would probably either inhibit or stimulate activity of a variety of hematopoietic cell types based solely on a limited sequence similarity to a cytokine which is a member of a family of cytokines characterized by a wide and diverse range of activities is an assertion of use which is so vague that it is meaningless. Therefore, antibodies to the IL-B50 polypeptide similarly lack a specific, substantial and credible utility.

As stated by the U.S. Court of Appeals for the Federal Circuit in *In re Fisher,* 2005 WL 2139421 (Sept. 7, 2005), disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." *Id.*

In summary, all of the biological activities of a protein need not be known to obtain a patent, but there must be some specific and substantial activity or function known. Neither the 09/399,492, filed September 29, 1999, nor the provisional applications to which it claims the benefit of priority, 60/101,318 and 60/131,298, disclose a patentable utility for the IL-B50 polypeptide or antibodies thereto.

Thus, because the '492 application does not disclose how to use antibodies that bind SEQ ID NO: 2, the priority of the filing date of that application (and the earlier filed provisional applications 60/131,298 and 60/101,318) is ***denied***, see MPEP 201.11.

(note that U.S.C. § 120 states that the disclosure of the invention in the prior application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112).

Therefore, the effective filing date of the instant claims is September 25, 2001 because it was only with the filing of 09/963,347 on September 25, 2001 that a utility for the polypeptide of SEQ ID NO: 2, and the antibodies that bind said sequence, was established.

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
September 27, 2007

MICHAIL BELYAVSKYI, PH.D.
PATENT EXAMINER

10/01/07